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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,645	10/27/2003	Ko-Pen Wang	2607-0002	8916

7590 01/24/2006

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EXAMINER

APANIUS, MICHAEL

ART UNIT PAPER NUMBER

3736

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/693,645

Applicant(s)

WANG, KO-PEN

Examiner

Michael Apanius

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11172003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because it contains more than 150 words. Correction is required. See MPEP § 608.01(b).
2. The disclosure is objected to because of the following informality: at page 15, line 3, it appears that "the first grippable cap member 34" should be --the second grippable cap member 36--. Appropriate correction is required.

Claim Objections

3. Claim 4 is objected to because of the following informalities: at claim 4, line 3, "member" should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 15-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. At claims 15-26, the recitations of "the device" lack proper antecedent basis. Note that claim 14, line 1 recites "A tissue collection device" and that claim 14, line 11

recites "a sampling device" and therefore a simple recitation of "the device" does not differentiate between the two devices recited in claim 14.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-9, 12, 14-17, 19-24, 27-31 and 33-35 are rejected under 35

U.S.C. 102(b) as being anticipated by Wang (US 4,966,162).

9. In regards to claim 1, Wang discloses a medical device (see figures 3, 5, 10 and 12; column 9, line 58 - column 11, line 39), comprising: a flexible outer tubular member (210) having proximal and distal ends; an inner tubular member (128) having proximal and distal ends slidably and coaxially received within the outer tubular member, a flexible inner stylet (218) having proximal and distal ends slidably and coaxially received within the inner tubular member; a spring member (252) having proximal and distal ends oriented adjacent the distal end of the outer tubular member, the spring member being coaxially received within the outer tubular member and surrounding a portion of the inner stylet, wherein the proximal end of the spring member is coupled to the stylet (a coaxial attachment wherein the stylet extends through the spring member); a retractable outer hollow needle member (254) having a proximal end coupled to the distal end of the spring member; and a retractable inner hollow needle member (256) slidably and

coaxially received within the outer hollow needle member and having a proximal end coupled to the distal end of the stylet; wherein the device has a retracted position wherein the inner and outer hollow needle members are completely housed within the outer tubular member, a first extended position wherein the outer hollow needle member and a first length of the inner hollow needle member extend beyond the distal end of the outer tubular member (and before limiting member 258 contacts tip 222), and a second extended position wherein the outer hollow needle member and a second length of the inner hollow needle member extend beyond the distal end of the outer tubular member (and after the limiting member 258 contacts tip 222), the second length being longer than the first length.

10. In regards to claim 2, the spring member is more compressed in the second extended position than in the first extended position.

11. In regards to claim 3, the device further comprises a hard tip (222) rigidly fixed to the distal end of the outer tubular member, the tip including a bearing surface on the proximal end thereof.

12. In regards to claim 4, the outer hollow needle member comprises a limiting member (258) rigidly associated with the outer hollow needle member and contacting the bearing surface of the tip member in the first and second extended positions.

13. In regards to claim 5, the spring member comprises a first spring (distal portion of 252) having proximal and distal ends and a second spring (proximal portion of 252) having proximal and distal ends, and wherein the first spring is oriented distally with respect to the second spring, and wherein the distal end of the first spring is attached to

the outer hollow needle member, and the proximal end of the second spring is attached to the stylet. Note that spring 252 can be interpreted to be two separate springs integrally formed together and that claim 35 supports this interpretation.

14. In regards to claim 6, the first spring comprises a first wavelength and the second spring comprises a second wavelength (measured across multiple gaps 266) greater than the first wavelength in the first extended position.

15. In regards to claim 7, the second spring comprises a third wavelength in the second extended position, the third wavelength being less than the second wavelength (this results from the spring being compressed in the second extended position).

16. In regards to claim 8, the gaps can alternatively be positioned anywhere along the length of the spring (column 10, lines 60-63) including only within the first spring. Therefore, the second wavelength can alternatively be less than the first wavelength (which alternatively includes gaps 266) in the first extended position.

17. In regards to claim 9, the inner tubular member comprises a biasing member (158) biasing the inner tubular member into a contacting relationship with a second bearing surface (156) to prevent retractable movement of the inner tubular member when in the retracted position.

18. In regards to claim 12, the inner tubular member is attached to a first grippable cap member (124), and the stylet is attached to a second grippable cap member (126).

19. In regards to claim 17, a sampling device comprises a sharp edge on the distal end of the inner hollow needle member.

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20. In regards to claim 27, the device has a luer lock member (110) connectable to an aspirating device (122).

21. In regards to claim 30, the device has a rigid fixed tubular member (154) having proximal and distal ends and coaxially received within the outer tubular member, wherein the proximal end of the fixed tubular member is attached to the luer lock member, and wherein the fixed tubular member coaxially houses a portion of the inner tubular member and a portion of the stylet.

22. In regards to claim 31, a limiting member (158) fixed to the inner tubular member, wherein the limiting member biasly acts against the distal end of the fixed tubular member to prevent removal of the inner tubular member from the medical device.

23. In regards to claims 14-16, 19-24, 27-29 and 33-35, the limitations are met as discussed above.

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25. Claims 13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (US 4,966,162) in view of Haaga (US 5,394,887). Wang does not expressly disclose that the inner hollow needle member can alternatively have a side gap which includes a trocar edge. Haaga teaches a needle member (10A) having a side gap (32)

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which includes a trocar edge (34) for the purpose of optimizing the quantity of tissue which can be removed from a biopsy site (column 3, lines 30-33). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used an inner needle member having a side gap which includes a trocar edge in the device of Wang as taught by Haaga in order to optimize the quantity of tissue which can be removed from a biopsy site.

26. Claims 10, 11, 25, 26 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (US 4,966,162) in view of Wang (US 4,532,935). Wang (US 4,966,162) does not expressly disclose that the stylet includes a limiting surface which limits proximal motion when the limiting surface is biased against the distal end of the inner tubular member. Wang (US 4,532,935) teaches stylet having a kink (216) for the purpose of ensuring rigidity of the stylet during advancement (column 7, lines 37-53). A kink similar to that of Wang (US 4,532,935), if employed in a device similar to that of Wang (US 4,966,162), would be capable of limiting proximal motion of the stylet when the kink is biased against the distal end of the inner tubular member. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a kink in the stylet of Wang (US 4,966,162) as taught by Wang (US 4,532,935) in order to ensure rigidity of the stylet during advancement.

Conclusion

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,022,363 discloses a rotatable dynamic seal and guide for a medical obstruction treatment device sub-assembly coupled to a motor drive unit. US 6,110,127 discloses a medical instrument for use in combination with an endoscope. US 6,514,215 discloses an endoscopic tissue collecting instrument.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8:30am-5pm.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA


CHARLES MARMOR
PRIMARY EXAMINER